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December 16, 2005

VIA E-FILING

The Hon. Kent A. Jordan
USDC for the District of Delaware
844 King Street
Wilmington, DE 19801

Re: In Re: '318 Patent Infringement Litigation
No. 05-356 (KAJ) (Consolidated) (D. Del.)

Your Honor:

My firm, along with Rakoczy Molino Mazzochi Siwik LLP, represent Defendants Mylan Pharmaceuticals Inc. and Mylan Laboratories Inc., in the captioned consolidated litigation. On behalf of all Defendants, we write in accordance with Section 4(f) of the current Scheduling Order and Your Honor's Civil Trial Procedures concerning a dispute that has arisen between the parties. As required, Defendants have scheduled a telephone conference with the Court to discuss this dispute. The Court has scheduled that call for December 20, 2005, at 10:00 a.m. EST. In general, this dispute relates to our letter submitted to the Court on November 10, 2005, concerning the proposed Stipulation Not to Contest Infringement (*see* D.I. 43), the subsequent filing of the Stipulation as executed by all parties (*see* D.I. 49), and Defendants' request for an earlier trial date in light of this, and other, significant concessions.

As Your Honor may recall, this Hatch-Waxman patent case concerns just two claims from a single method-of-use patent, which expires on December 14, 2008. When the parties appeared before the Court at the October 12, 2005 status conference, this consolidated case involved seven different ANDAs containing allegedly infringing products, as well as invalidity counterclaims. At the conference, the Court entered a discovery schedule ordering a 10-day bench trial now set for October 2007. Significantly, however, the Court indicated that a shorter discovery schedule and earlier trial date would be appropriate if the Defendants: (1) did not contest infringement; and (2) agreed to use common experts. More specifically, the Court engaged in the following exchange with defense counsel:

> MR. GRACEY [counsel for defendant Barr]: . . . The other thing is, I just want to indicate, if we come to the point, we defendants, whereby one or all of us concede that, yes, the ANDA would fall within these claims, thereby truncating any need for long delayed discovery on alleged infringement and it really just comes down to a validity case, I really think that would significantly speed up the trial date, particularly with it being a bench trial, and cut back the amount of discovery time.
>
> THE COURT: I don't disagree. Well, go ahead and surprise me. Because it would surprise me if – but I would be delighted to be surprised, Mr. Gracey, if everybody said, 'You know what? We confess infringement. This is only a validity case. We're going to cooperate with your experts. We're going to have combined experts.' ***And then this case goes from a two-week bench trial to a three-or-four day bench trial, and you can bring it on in. Hey, we can do it in a year.***

(10/12/2005 Tr. at 28-29, D.I. 25 (emphasis added), Exhibit 1). Defendants now have done both of the things that the Court suggested would allow this litigation to proceed on an expedited basis, *i.e.*, Defendants have (1) filed a fully executed Stipulation Not to Contest Infringement; and (2) notified Plaintiffs that Defendants will use common experts in this litigation. In light of these significant concessions, Defendants set about preparing a revised Scheduling Order. While the Court had suggested that the case could be completed in as little as a year, Defendants did not propose such a schedule. Indeed, hoping to reach agreement with Plaintiffs, Defendants proposed a schedule very similar to the one that they offered back in October when this consolidated case involved seven individual infringement determinations.

Under Defendants' revised Discovery Schedule, the deadline for completing all discovery is shortened by approximately six months, and the trial is moved up approximately seven and a half months, from October 2007 (as currently scheduled) to February 2007. (A copy of Defendants' proposed [Revised] Scheduling Order is attached as Exhibit 2 hereto.) Defendants believe that their proposed revisions to the current Scheduling Order are reasonable in light of the considerable concessions they that have made in an effort to expedite this Hatch-Waxman litigation. Twenty months is more than enough time to complete a case involving the validity of two claims from a single, 3-page method-of-use patent.[1] Equally as important, Defendants believe that their proposal is consistent with the Court's expectations, as suggested at the October 12 status hearing.

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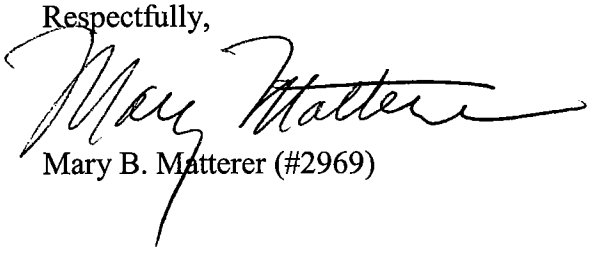
[1] Plaintiffs brought suit in June 2005 and Defendants propose a February 2007 trial date.

Defendants provided Plaintiffs with the proposal discussed above. Despite having Defendants' concessions in hand, Plaintiffs delayed responding for two weeks. When they ultimately did write back, Plaintiffs' response to Defendants' proposal indicated that Plaintiffs lacked a genuine interest in attempting to advance this litigation.[2] Specifically, Plaintiffs, arguing that Defendants' proposal "unduly truncates discovery and other proceedings in this case," proposed a revised schedule that would do little, if anything, to expedite this litigation, even though the litigation now no longer involves seven infringement determinations. For example, Plaintiffs propose to shorten the deadline for fact discovery by just twenty-nine days and the period for completing all discovery by less than two months; and to move the trial up by less than a month and a half, to August 2007. Plaintiffs otherwise propose to modify remaining relevant dates in the Scheduling Order by only between one to two months. Plaintiffs' proposal would unduly prolong this substantially narrowed Hatch-Waxman litigation and, unlike Defendants' proposal, is inconsistent with the Court's discussion at the October 12 status conference. (A copy of Plaintiffs' proposed [Revised] Scheduling Order is attached as Exhibit 3 hereto.)

Defendants respectfully request that the Court enter their proposed [Revised] Scheduling Order so that this ANDA litigation can reach an expeditious resolution, as contemplated by the controlling statutory scheme. For the Court's convenience, a chart summarizing relevant dates in the current Scheduling Order, in addition to the parties' current positions for a revised Order, is attached hereto as Exhibit 4. We look forward to speaking with your Honor regarding these matters on December 20. Thank you for your consideration.

Respectfully,



Mary B. Matterer (#2969)

MBM/cdl
Enclosures

cc: Clerk of the Court (via electronic filing)
Service list – attached (via e-mail)

[2] At Defendants' request, the parties also held a meet-and-confer teleconference on December 9, 2005, but failed to reach agreement on terms for a truncated discovery schedule. Counsel for Mylan contacted the Court that afternoon to schedule a conference.

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